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December 15, 1998

Office of Special Nutritional (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street SW Washington, DC 20204

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## Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

**Promotes a Healthy Urinary Tract** 

Cranberry juice has been used historically to help maintain normal function of the urinary tract.

on the following product:

Tree of Life® Cranberry

Very truly yours,

Leiner, Health Products

Gale Bensússen, President

cc: Michael Bradley, Director of Regulatory Affairs William Cochran, Manager of Regulatory Affairs